

# **Changes in predictive capacity when adding Ticagrelor and Clopidogrel to an existing allogeneic bloodtransfusio prediction model for cardiac surgery.**

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**Ethische beoordeling**

Positief advies

**Status**

Werving gestart

**Type aandoening**

-

**Onderzoekstype**

Observationeel onderzoek, zonder invasieve metingen

## **Samenvatting**

### **ID**

NL-OMON22097

### **Bron**

NTR

### **Verkorte titel**

RUBY

### **Aandoening**

Coronary heart disease, valvular disease, vascular disease

### **Ondersteuning**

**Primaire sponsor:** Department of Cardiac Surgery and Department of Anesthesia  
Amsterdam UMC

**Overige ondersteuning:** None

### **Onderzoeksproduct en/of interventie**

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

How accurately does the TRACK model predict allogeneic blood transfusions in the Amsterdam UMC, location AMC, cardiothoracic surgery population?

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

The Transfusion Risk and Clinical Knowledge (TRACK) model was developed in 2008 in an Italian adult cardiac surgery population and consists of the following 5 predictive factors: sex, age, weight, pre-operative haematocrit and complexity of surgery(6). The decision to use this specific model was based on its simplicity and relatively high predictive capacity, in comparison to other models with higher numbers of complex factors. This model has an allogeneic blood transfusion predictive capacity of 72% and uses a point system to divide patients into different risk groups, according to the total number of points allocated. During the derivation of this model in 2008, dual anti-platelet medication was included, but no significant association was found. In the 12 years since development, the popularity of dual anti-platelet medication used in acute coronary syndrome patients, has significantly improved and its association with post-operative bleeding and allogeneic blood transfusion has been suggested(10, 11).

Validating this model might aid clinicians in reducing allogeneic blood transfusions, transfusion complications and associated costs. Ultimately this might aid development of patient specific transfusion strategies and new blood management protocols.

The aim of this study is to externally validate the TRACK blood transfusion prediction model in our population. Additionally, we will study the impact of adding the preoperative use of dual antiplatelet medication, as extra predictive factor, to the TRACK blood transfusion prediction model and determine the effect on predictive capacity.

### **Doel van het onderzoek**

The aim of this study is to externally validate the TRACK blood transfusion prediction model in our population. Additionally, we will study the impact of adding the preoperative use of dual antiplatelet medication, as extra predictive factor, to the TRACK blood transfusion prediction model and determine the effect on predictive capacity.

### **Onderzoeksopzet**

Pre operative: Baseline Characteristic, Vital Signs, Laboratory values, transfusions,  
Intraoperative: Extracorporeal Characteristics, Vital Signs, Laboratory values, transfusions

Post operative: Vital Signs, Laboratory values, transfusions, 30 day mortality, 90 day mortality

### **Onderzoeksproduct en/of interventie**

none

## **Contactpersonen**

### **Publiek**

Amsterdam UMC, Location Amc  
Renard Haumann

0650051198

### **Wetenschappelijk**

Amsterdam UMC, Location Amc  
Renard Haumann

0650051198

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

- Patients > 18 years
- Patients receiving on-pump cardiac surgery.
- Patients receiving off-pump cardiac surgery.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

A potential patient who meets any of the following criteria will be excluded from participation in the data collection:

- Cardiac surgery for congenital disorders

# Onderzoeksopzet

## Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	12-05-2021
Aantal proefpersonen:	3500
Type:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies	
Datum:	11-05-2021
Soort:	Eerste indiening

## Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## **Andere (mogelijk minder actuele) registraties in dit register**

Geen registraties gevonden.

## **In overige registers**

<b>Register</b>	<b>ID</b>
NTR-new	NL9464
Ander register	METC Location AMC : W21_265 # 21.291

## **Resultaten**